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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/741,215	12/19/2000	Qi Jia	UNI.15/D	7672

25871 7590 05/06/2003

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EXAMINER

PATTEN, PATRICIA A

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 05/06/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/471,215

Applicant(s)

Arvada et al.

Examiner

Patricia Patten

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 18, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 15, 16, 19, 23, and 26 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 15, 16, 19, 23, and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Claims 13, 15-16, 19, 23 and 26 remain pending in the application and were examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Arguments presented 2/18/03 which pertain solely to the prior rejections are moot in light of the new rejections which follow.

Claim Rejections - 35 USC § 102

Claims 13, 15-16, 23 and 26 are newly rejected under 35 U.S.C. 102(b) as being anticipated by Boulware et al. (1980) as further evidenced by Southard et al. (US 5,013,553).

Boulware et al. (1980) taught that magnoflorine, a composition which satisfies the requirements of the structure in Instant claim 1 (please see Structure 1, p.201) was inherent to species of Zanthoxylum which is evidenced by the (RESULTS section,

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p.200). Boulware et al. specifically outlined an extraction protocol which included: extraction with hexane followed by methanol, dissolving the methanol residue in 1 M sulfuric acid, extraction with chloroform, neutralization via ammonium hydroxide (to pH 6), extraction with butanol and evaporation (concentration), dissolving in methanol and purification via silica gel (p.203, Experimental). Because the reference teaches every method step recited in the Instant claims, the reference anticipates the claimed invention.

Applicants contend that the claimed compounds cannot be purified on silica gel :
“It is well known in the art that adsorption phase silica gel chromatography cannot be used to purify charged compounds because irreversible absorption and the difficulty involved in eluting these compounds from the column will lead to very low recovery of the compound of interest” (p.11-Arguments). This is argument by counsel which has not been substantiated by clear evidence. First, silica gel is well known in the art for being used as an ion-exchange resin. Applicants contend that the claimed compounds cannot be purified on silica gel due to their positively charged quaternary ammonium structure, however have clearly shown in the Instant specification that chelerythrine, which has a positively charged quaternary ammonium structure, was purified on silica gel (p.13). Further, Southard et al. also taught that sanguilutine, which has a quaternary ammonium structure was purified on silica gel (col.4, lines 67-col. 5, line 2). Thus, this statement appears to contradict what is found in the Instant specification as

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well as the prior art. It is deemed that silica gel is a type of ion exchange column, and therefore satisfies the chromatographic method as found in part (c) of claim 1.

Claim Rejections - 35 USC § 103

Claims 13, 15-16, 19, 23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boulware et al. (1980).

The teachings of Boulware et al. were taught supra. Boulware et al. did not specifically teach where the silica gel was in a column extractor as recited in claim 19.

One of ordinary skill in the art would have been motivated to have purified magnoflorine in a column extractor in order to achieve an optimized yield of product. It was clear from the teaching of Boulware et al. that the plc (similar to a tlc prep) was used to quantify phytochemicals resulting from the trial extraction procedure performed on Zanthoxylum bark extract. Thus, the ordinary artisan would have recognized that purification of magnoflorine via a column extractor with silica gel would have been advantageous with regard to a larger scale extraction.

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From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

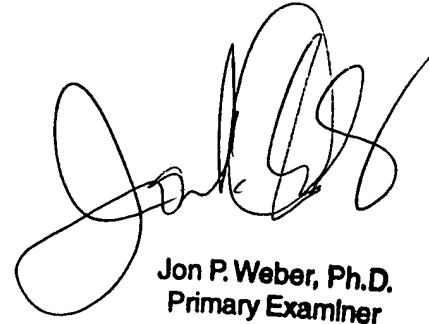
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback is on 703-306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Jon P. Weber, Ph.D.
Primary Examiner